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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**AXSOME THERAPEUTICS, INC. and  
ANTECIP BIOVENTURES II LLC,**

**Plaintiffs,**

**v.**

**TEVA PHARMACEUTICALS, INC.,**

**Defendant.**

**Civil Action No. 23-1695 (MEF)(LDW)**

**(Filed Electronically)**

**AXSOME THERAPEUTICS, INC. AND ANTECIP  
BIOVENTURES II LLC'S ANSWER TO TEVA  
PHARMACEUTICALS, INC.'S COUNTERCLAIMS**

Axsome Therapeutics, Inc. ("Axsome") and Antecip Bioventures II LLC ("Antecip") (collectively, "Plaintiffs"), by their undersigned attorneys, hereby answer the Counterclaims to Plaintiffs' Complaint for Patent Infringement by Teva Pharmaceuticals, Inc. ("Teva"), dated May 30, 2023, as follows. Except as expressly admitted, all allegations are denied.

## **COUNTERCLAIMS**

### **PARTIES**

1. Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

**ANSWER:** On information and belief, Plaintiffs admit the allegations of paragraph 1.

2. On information and belief, Axsome is a corporation existing under the laws of Delaware, having a principal place of business at 22 Cortland Street, 16th Floor, New York, NY 10007.

**ANSWER:** Plaintiffs admit that Axsome is a corporation existing under the laws of Delaware and that its principal place of business as of the filing of the Complaint was 22 Cortland Street, 16th Floor, New York, NY 10007, and, except as so admitted, deny the allegations of paragraph 2.

3. On information and belief, Antecip is a limited liability corporation existing under the laws of Delaware, having a principal place of business at 630 Fifth Avenue, Suite 200, New York, NY 10111.

**ANSWER:** Plaintiffs admit the allegations of paragraph 3.

### **JURISDICTION AND VENUE**

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**ANSWER:** Paragraph 4 states legal conclusions for which no answer is required. To the extent that an answer is required, Plaintiffs admit that this Court has declaratory judgment jurisdiction over Teva's Counterclaims as to the patents-in-suit, admit that there is an actual and justiciable controversy between the parties, but Plaintiffs deny that Teva is entitled to any of the relief that it seeks, and, except as so admitted, deny the allegations of paragraph 4.

5. The Court has original jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Paragraph 5 states legal conclusions for which no answer is required. To the extent that an answer is required, Plaintiffs admit that this Court has subject matter jurisdiction over Teva's Counterclaims as to the patents-in-suit for purposes of this specific action only, admit that there is an actual and justiciable controversy between the parties, but Plaintiffs deny that Teva is entitled to any of the relief that it seeks, and, except as so admitted, deny the allegations of paragraph 5.

6. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges, and have subjected themselves to the jurisdiction, of this Court by filing this action and/or because Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

**ANSWER:** Paragraph 6 states legal conclusions for which no answer is required. To the extent that an answer is required, Plaintiffs admit that this Court has personal jurisdiction over Plaintiffs for the purposes of adjudicating Teva's Counterclaims as to the patents-in-suit, deny that Teva is entitled to any of the relief that it seeks, and, except as so admitted, deny the allegations of paragraph 6.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

**ANSWER:** Paragraph 7 states legal conclusions for which no answer is required. To the extent that an answer is required, Plaintiffs admit that venue is proper to adjudicate this action, and, except as so admitted, Plaintiffs deny the allegations of paragraph 7.

### **FACTUAL BACKGROUND**

8. According to the United States Food and Drug Administration ("FDA") publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), Axsome is the holder of New Drug Application ("NDA") No. 215430 for Auvelity®, a combination of dextromethorphan hydrobromide and bupropion hydrochloride.

**ANSWER:** Plaintiffs admit the allegations of paragraph 8.

9. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

**ANSWER:** Paragraph 9 states legal conclusions for which no answer is required. To the extent that an answer is required, Plaintiffs admit that 21 C.F.R. U.S.C. §§ 355(b)(1)(A)(viii), 355(j)(7)(A)(iii) contain statutory provisions relating to food and drugs, including publication by the FDA of the “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly called the “Orange Book,” refer to the regulations for the terms thereof, and, except as so admitted, deny the allegations of paragraph 9.

10. As of May 30, 2023, the Orange Book entry for Auvelity® lists 106 patents. Four of these patents include United States Patent Nos. 10,780,064 (“the ’064 patent”), 10,925,842 (“the ’842 patent”), 10,940,124 (“the ’124 patent”), and 10,966,942 (“the ’942 patent”) (collectively, “the patents-in-suit”).

**ANSWER:** Plaintiffs admit the allegations of paragraph 10.

11. The face of the ’064 patent lists the title as “Bupropion as a Modulator of Drug Activity,” the issue date as September 22, 2020, and the assignee as Antecip.

**ANSWER:** Plaintiffs admit that on September 22, 2020, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’064 patent, titled, “Bupropion as a Modulator of Drug Activity,” admit that Antecip and Axsome are the owner and exclusive licensee, respectively, of the ’064 patent, and, except as so admitted, deny the allegations of paragraph 11.

12. The face of the ’842 patent lists the title as “Bupropion as a Modulator of Drug Activity,” the issue date as February 23, 2021, and the assignee as Antecip.

**ANSWER:** Plaintiffs admit that on February 23, 2021, the USPTO duly and lawfully issued the ’842 patent, titled, “Bupropion as a Modulator of Drug Activity,” that Antecip and Axsome are the owner and exclusive licensee, respectively, of the ’842 patent, and, except as so admitted, deny the allegations of paragraph 12.

13. The face of the '124 patent lists the title as “Bupropion as a Modulator of Drug Activity,” the issue date as March 9, 2021, and the assignee as Antecip.

**ANSWER:** Plaintiffs admit that on March 9, 2021, the USPTO duly and lawfully issued the '124 patent, titled, “Bupropion as a Modulator of Drug Activity,” that Antecip and Axsome are the owner and exclusive licensee, respectively, of the '124 patent, and, except as so admitted, deny the allegations of paragraph 13.

14. The face of the '942 patent lists the title as “Bupropion as a Modulator of Drug Activity,” the issue date as April 6, 2021, and the assignee as Antecip.

**ANSWER:** Plaintiffs admit that, on April 6, 2021, the USPTO duly and lawfully issued the '942 patent, titled, “Bupropion as a Modulator of Drug Activity,” that Antecip and Axsome are the owner and exclusive licensee, respectively, of the '942 patent, and, except as so admitted, deny the allegations of paragraph 14.

15. Antecip purports to own, and to have the right to enforce, the patents-in-suit.

**ANSWER:** Plaintiffs admit that Antecip is the owner of the patents-in-suit, that it has the right to enforce each of the patents-in-suit against Teva in this action, and, except as so admitted, deny the allegations of paragraph 15.

16. Axsome purports to be an exclusive licensee of the patents-in-suit and to have the right to enforce the patents in-suit.

**ANSWER:** Plaintiffs admit that Axsome is the exclusive licensee of the patents-in-suit, that it has the right to enforce each of the patents-in-suit against Teva in this action, and, except as so admitted, deny the allegations of paragraph 16.

17. Teva submitted Abbreviated New Drug Application (“ANDA”) No. 218147 (“Teva’s ANDA”) to the FDA under 21 U.S.C. § 355(j) seeking approval to market Teva’s proposed Dextromethorphan Hydrobromide and Bupropion Hydrochloride Extended-release Tablets, 45 mg/105 mg (“the Teva ANDA Product”). Teva submitted Teva’s ANDA to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit.

**ANSWER:** Plaintiffs admit on information and belief that Teva submitted ANDA No. 218147 to obtain FDA approval to engage in the commercial manufacture, use, importation, distribution, and/or sale of Teva's proposed dextromethorphan hydrobromide and bupropion hydrochloride extended-release tablets, 45 mg/105 mg ("Teva's ANDA Product") prior to the expiration of the patents-in-suit. Plaintiffs also admit on information and belief that Teva's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the claims of the '064 patent, the '842 patent, the '124 patent, and the '942 patent, but Plaintiffs deny the legitimacy of Teva's allegations in its ANDA. Except as so admitted, Plaintiffs deny the allegations of paragraph 17.

18. Teva sent notice of this certification to Counterclaim-Defendants on or about February 9, 2023 ("Teva's Notice Letter"). On information and belief, and as Counterclaim-Defendants allege in the Complaint, Counterclaim-Defendants received Teva's Notice Letter.

**ANSWER:** Plaintiffs admit that Axsome received a letter dated February 9, 2023 ("Teva's Notice Letter"), in which Teva notified Plaintiffs that Teva's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the claims of the '064 patent, the '842 patent, the '124 patent, and the '942 patent, but Plaintiffs deny the legitimacy of Teva's arguments in its Notice Letter. Except as so admitted, Plaintiffs deny the allegations of paragraph 18.

19. On March 24, 2023, Counterclaim-Defendants filed suit in this Judicial District against Teva in connection with Teva's ANDA, alleging Teva's infringement of the patents-in-suit.

**ANSWER:** Plaintiffs admit the allegations of paragraph 19.

### **FIRST COUNTERCLAIM**

#### **Declaratory Judgment of Noninfringement of the '064 Patent**

20. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

21. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '064 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of Paragraph 21.

22. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '064 patent.

**ANSWER:** Plaintiffs deny the allegations of paragraph 22.

23. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgement regarding Teva's non-infringement of the '064 patent.

**ANSWER:** Paragraph 23 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable controversy between the parties regarding the '064 patent and, except as so admitted, deny the allegations of paragraph 23.

24. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '064 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of paragraph 24.

## **SECOND COUNTERCLAIM**

### **Declaratory Judgment of Invalidity or Unenforceability of the '064 Patent**

25. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

26. The claims of the '064 patent are invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

**ANSWER:** Plaintiffs deny the allegations of paragraph 26.

27. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '064 patent.

**ANSWER:** Paragraph 27 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable case or controversy between the parties regarding the '064 patent and, except as so admitted, deny the allegations of paragraph 27.

28. Teva is entitled to a judicial declaration that the claims of the '064 patent are invalid and/or unenforceable.

**ANSWER:** Plaintiffs deny the allegations of paragraph 28.

### **THIRD COUNTERCLAIM**

#### **Declaratory Judgment of Noninfringement of the '842 Patent**

29. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

30. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '842 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of paragraph 30.

31. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '842 patent.

**ANSWER:** Plaintiffs deny the allegations of paragraph 31.

32. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Teva's non-infringement of the '842 patent.



**ANSWER:** Paragraph 32 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable controversy between the parties regarding the '842 patent and, except as so admitted, deny the allegations of paragraph 32.

33. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '842 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of paragraph 33.

#### **FOURTH COUNTERCLAIM**

##### **Declaratory Judgment of Invalidity or Unenforceability of the '842 Patent**

34. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

35. The claims of the '842 patent are invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

**ANSWER:** Plaintiffs deny the allegations of paragraph 35.

36. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '842 patent.

**ANSWER:** Paragraph 36 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable case or controversy between the parties regarding the '842 patent and, except as so admitted, deny the allegations of paragraph 36.

37. Teva is entitled to a judicial declaration that the claims of the '842 patent are invalid and/or unenforceable.

**ANSWER:** Plaintiffs deny the allegations of paragraph 37.

### **FIFTH COUNTERCLAIM**

#### **Declaratory Judgment of Noninfringement of the '124 Patent**

38. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

39. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '124 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of paragraph 39.

40. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '124 patent.

**ANSWER:** Plaintiffs deny the allegations of paragraph 40.

41. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgement regarding Teva's non-infringement of the '124 patent.

**ANSWER:** Paragraph 41 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable controversy between the parties regarding the '124 patent and, except as so admitted, deny the allegations of paragraph 41.

42. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '124 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of paragraph 42.

## **SIXTH COUNTERCLAIM**

### **Declaratory Judgment of Invalidity or Unenforceability of the '124 Patent**

43. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

44. The claims of the '124 patent are invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

**ANSWER:** Plaintiffs deny the allegations of paragraph 44.

45. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '124 patent.

**ANSWER:** Paragraph 45 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable case or controversy between the parties regarding the '124 patent and, except as so admitted, deny the allegations of paragraph 45.

46. Teva is entitled to a judicial declaration that the claims of the '124 patent are invalid and/or unenforceable.

**ANSWER:** Plaintiffs deny the allegations of paragraph 46.

## **SEVENTH COUNTERCLAIM**

### **Declaratory Judgment of Noninfringement of the '942 Patent**

47. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

48. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '942 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of paragraph 48.

49. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '942 patent.

**ANSWER:** Plaintiffs deny the allegations of paragraph 49.

50. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgement regarding Teva's non-infringement of the '942 patent.

**ANSWER:** Paragraph 50 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable controversy between the parties regarding the '942 patent and, except as so admitted, deny the allegations of paragraph 50.

51. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '942 patent, either directly or indirectly.

**ANSWER:** Plaintiffs deny the allegations of paragraph 51.

### **EIGHTH COUNTERCLAIM**

#### **Declaratory Judgment of Invalidity or Unenforceability of the '942 Patent**

52. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Plaintiffs incorporate their responses to the preceding paragraphs.

53. The claims of the '942 patent are invalid and/or unenforceable for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

**ANSWER:** Plaintiffs deny the allegations of paragraph 53.

54. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the

issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '942 patent.

**ANSWER:** Paragraph 54 states legal conclusions for which no answer is required. To the extent an answer is required, Plaintiffs admit that there is an actual, substantial, and continuing justiciable case or controversy between the parties regarding the '942 patent and, except as so admitted, deny the allegations of paragraph 54.

55. Teva is entitled to a judicial declaration that the claims of the '942 patent are invalid and/or unenforceable.

**ANSWER:** Plaintiffs deny the allegations of paragraph 55.

#### **PRAYER FOR RELIEF**

Plaintiffs deny that Teva is entitled to any relief on its Counterclaims, either as prayed for in its pleading or otherwise.

#### **PLAINTIFFS' AFFIRMATIVE DEFENSE**

Without prejudice to the denials set forth in this Answer and to the ability to amend this Answer to seek and allege any and all defenses not presently known or that are revealed during the course of discovery or otherwise, Plaintiffs assert the following affirmative defense in response to Teva's Counterclaims:

#### **Failure to State a Claim**

The Counterclaims fail to state any claim for which relief may be granted.

Dated: June 20, 2023

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